

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

CAROL LEWIS,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.:
)	1:15-CV-13530-NMG
)	
ALEX AZAR)	
Secretary, United States Department)	
of Health and Human Services,)	
)	
Defendant.)	
_____)	

DEFENDANT’S REPLY TO PLAINTIFF’S REQUEST FOR STATUS CONFERENCE

The Secretary of the Department of Health and Human Services (“the Secretary” or “Defendant”), replies to Plaintiff’s Request for Status Conference as follows:

I. PLAINTIFF’S REQUEST FOR A STATUS CONFERENCE IS PREMATURE BECAUSE PLAINTIFF HAS NOT YET ESTABLISHED THAT THIS COURT HAS SUBJECT MATTER JURISDICTION OVER HER COMPLAINT.

Ab initio, Plaintiff’s Request is not essentially a request for a conference on the pleadings that she has previously filed, but, rather a vehicle for attempting to present further argument on her claims. Plaintiff argues here that a status conference to determine whether the Defendant is barred by collateral estoppel from contesting the issues raised in the Complaint. Pl.’s Mot. for Hearing Req. for Status Conference, Doc. 72, at 1. Her request for a status conference is inapposite because Plaintiff has not established that this Court has subject matter jurisdiction over her claim, and subject matter jurisdiction must be determined prior to making a determination on her collateral estoppel argument.

On August 18, 2017, this Court dismissed the Complaint, holding that it lacked subject matter jurisdiction because the claims were moot. Mem. & Order, Doc. 58, at 5. The Court

concluded that because Plaintiff no longer was using the continuous glucose monitoring equipment (CGM) that was the subject of her Complaint, she lacked a legal interest in the outcome of the case. *Id.* at 4. On September 18, 2017, Plaintiff filed a Motion to Alter or Amend Judgment contesting the Court's holding that her claim was moot and requesting amendment of the judgment. Pl.'s Mot. to Amend or Alter J., Doc. 60. On October 2, 2017, Defendant filed its Opposition to Plaintiff's Motion to Alter or Amend Judgment. Def.'s Opp'n to Pl.'s Motion to Amend or Alter J., Doc. 61. The Court has not yet ruled on the Plaintiff's September 18, 2017, Motion, and, accordingly, the issue of mootness – and jurisdiction -- is outstanding.¹

Consequently, Plaintiff's request for a status conference is premature because this Court must revisit the issue of mootness before proceeding to evaluate, if the Court deems it warranted to consider additional arguments in this labrythine case, Plaintiff's further arguments on the merits. *See Am. Civil Liberties Union of Mass. V. U.S. Conf. of Catholic Bishops*, 705 F.3d 44, 52 (1st Cir. 2013) ("Mootness is a ground which should ordinarily be decided in advance of any determination on the merits), *citing Arizonans for Official English v. Az.*, 520 U.S. 43, 67 (1997). Plaintiff's Request for Status Conference does not introduce any new arguments in support of subject matter jurisdiction; rather, it argues that Defendant is barred by collateral estoppel from

¹ In footnote 2 of Plaintiff's Request for Status Conference, Plaintiff asserts that she has switched from using the Dexcom G5 (a device approved by the FDA and covered by Medicare pursuant to CMS Ruling No. 1682-R) to the Medtronic CGM. Pl.'s Mot. to Amend or Alter J., Doc. 60 at n2. Plaintiff offers no evidence to support this puzzling assertion. Even if true, it is unclear why Plaintiff raised it in this litigation. Plaintiff has not alleged any harm or damage related to her switch to the Medtronic device and any prospective future harm she may claim is insufficient to make the Complaint ripe for review. *See Am. Civil Liberties Union of Mass. V. U.S. Conf. of Catholic Bishops*, 705 F.3d 44, 54 (1st Cir. 2013) (holding that in order "to withstand a mootness challenge, the facts alleged must show that there is a substantial controversy of sufficient immediacy and reality. . .").

contesting the issues set forth in the Complaint. This Court has pending motions from both parties addressing the issue of subject matter jurisdiction; thus, a status conference is not necessary on this issue. As a result, Plaintiff's Request for a Status Conference is premature and should be denied.

II. PLAINTIFF'S ARGUMENT THAT THE SECRETARY IS BARRED BY COLLATERAL ESTOPPEL FROM PROCEEDING IN THIS MATTER IS WITHOUT MERIT.

In event, Plaintiff's new argument is without merit. Plaintiff argues that because of the decisions in *Whitcomb v. Hargan*, Civil Case No. 17-CV-14 (D. Wis.) (2017) and *Bloom v. Azar*, Civil Case No. 16-CV-121 (D. Vt.) (2018),² the Secretary is barred by collateral estoppel from contesting the classification of CGMs as durable medical equipment ("DME") and the determination that CGMs are covered by Medicare. Plaintiff's arguments are without merit because Plaintiff has not established essential elements of collateral estoppel.

The Court is permitted to apply the doctrine of collateral estoppel where "(1) the issue sought to be precluded in the later action is the same as that involved in the earlier action; (2) the issue was actually litigated; (3) the issue was determined by a valid and binding final judgment; and (4) the determination of the issue was essential to the judgment." *Ramallo Bros. Printing, Inc. v. El Dia, Inc.*, 490 F.3d 86 (1st Cir. 2007). For the reasons set forth below, Plaintiff is unable to meet the first, second, or third elements of collateral estoppel and thus collateral estoppel is inappropriate here.

² The Secretary notes that this decision was issued on January 29, 2018, subsequent to the decision issued in this case.

**A. The Issues In This Case Are Separate And Distinct From The Issues
In Whitcomb And Bloom.**

Plaintiff fails to satisfy the first element of collateral estoppel because the issues in this action are separate and distinct from the issues in *Whitcomb* and *Bloom*.

The judicial review of an administrative decision regarding a claim for Medicare benefits is limited to review of the certified copy of the administrative record and relevant pleadings. 42 U.S.C. § 405(g); *see also Mathews v. Weber*, 423 U.S. 261, 263 (1976). As a result, in *Whitcomb* and *Bloom*, the litigation was limited to the issues raised in the administrative record and relevant pleadings and thus the issues involved in each case were necessarily different as they centered on the issues raised and supported by the corresponding administrative records and pleadings.

In addition, Plaintiff's request for Medicare coverage of a CGM involves an individual determination as to whether a CGM is reasonable and necessary for her based on the information included in the administrative record in her case. In order for Plaintiff to demonstrate that she is entitled to Medicare coverage of a CGM, she must demonstrate that (1) a CGM is eligible for coverage under a defined benefit category; (2) a CGM is reasonable and necessary for her diagnosis or treatment; and (3) a CGM is not otherwise excluded by provisions of the Medicare statute. 42 U.S.C. §§ 1395k, 1395x, 1395y(a)(1)(A),(B). In both *Whitcomb* and *Bloom*, the courts determined that coverage of a CGM was appropriate for the parties *only after* concluding that the administrative record supported a determination that the CGM was reasonable and necessary for Ms. Whitcomb and Dr. Bloom. *See Whitcomb Decision and Order*, at 15 (deferring to the Administrative Law Judge's determination that the CGM was medically reasonable and necessary for Ms. Whitcomb); *Bloom Opinion and Order*, at 24-25 (holding that, based on its review of Dr. Bloom's administrative record, the use of a CGM was reasonable and

necessary for Dr. Bloom). Accordingly, the issue of whether a CGM is appropriate for Plaintiff is an individual determination and is separate and distinct from the determinations made in *Whitcomb* and *Bloom*.

B. The Court In *Whitcomb* Did Not Fully Litigate The Issue Of Medicare Coverage Of CGMs.

Plaintiff is unable to meet the second element of collateral estoppel, when considering the *Whitcomb* case; because, in *Whitcomb*, while the Court concluded that CGMs were primarily and customarily used to serve a medical purpose, it acknowledged that the parties did not fully litigate whether CGMs otherwise satisfied the definition of durable medical equipment and/or whether a CGM was medically reasonable and necessary for Ms. Whitcomb. *Whitcomb*, at 15. The Court instead deferred to the ALJ's analysis of those issues, which did not address the issue of the definition of durable medical equipment. *Id.* Since neither party had an opportunity to fully litigate whether CGMs met the remaining requirements of durable medical equipment, the outcome in *Whitcomb* could not support estoppel here.

C. The Court's Decision In *Bloom* Is Not A Final And Binding Judgment

Last, Plaintiff is unable to meet the third element of collateral estoppel, when considering the *Bloom* case, because, the time to appeal the *Bloom* decision has not yet expired. As a result, the judgment is not yet final and binding and cannot be relied upon to estop the Secretary from litigating here.

III. CONCLUSION

For the foregoing reasons, Defendant requests that the Court deny Plaintiff's Request for a Status Conference.

Respectfully submitted,

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/s/ Anita Johnson

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Certificate of Service

I hereby certify that the foregoing will be filed through the electronic filing system of the Court, which system will served counsel for Plaintiff electronically, on this seventh day of March 2018.

/s/ Anita Johnson

Assistant U.S. Attorney